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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/695,022	10/23/2000	Steven Z. Wu	M-8873 US	3060

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 06/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/695,022

Applicant(s)

WU ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,8-11,21-25 and 27-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,8-11,21-25 and 27-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some \* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 18, 2004 has been entered.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaplan (US 5,342,348). Kaplan anticipates the claim language where the radially expanded body as claimed is stent (2) of Kaplan and the string as claimed is strand (14) or (16) of Kaplan; see Figure 1 and column 11, lines 5-20.

With regard to claim 29, Applicants are directed to column 6, lines 16-52 of Kaplan.

With regard to claim 31, Applicants are directed to column 7, lines 49-52 of Kaplan.

With regard to claims 28 and 32, an alternative embodiment of Kaplan is being applied here; see Figure 4A, 4B, and 5A to 5C. The expandable body structure as

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claimed is the coiled filament strand (52) of Kaplan and the string as claimed is filament (54) or (56), which is adhesively bonded to be formed together.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 4, 8, 9, 11, 21, 23, 24, 25, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burkoth et al (WO 98/23228) in view of Kaplan (US 5,342,348). Burkoth meets the claim language where the body structure is the stent (11) of Burkoth, and the string as claimed is the polymeric matrix (27) of Burkoth; see especially Figures 2, 4, and 9 and pages 9, 13, and 16. However, Burkoth fails to disclose the degree of integrity of the polymeric matrix (27) of the invention but it is disclosed that it can be made of polyethylene-vinyl acetate; see page 13, lines 6-14. Kaplan teaches that polymeric matrices (see column 7, lines 13-17) can be made to have enough integrity to be wound or interlaced through perforations (see column 6, lines 19-24) and can be formed of the same polymer of polyethylene-vinyl acetate (see column 7, lines 42-52). Since the same polymer is used, the Examiner asserts that the same physical properties inherently exist such that the claims are at least obvious in view of Burkoth. At the minimum, it is the Examiner's position that it would have been *prima facie* obvious to make the polymeric matrix of Burkoth in the same manner as Kaplan so that it can be more easily handled during manufacturing.

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With regard to claims 3 and 4 specifically, by measuring the features of Figure 9 and since the depth of a groove in Brown's Figure 9 is about 16 mm and the diameter is about 43 mm, the groove of Brown is about 37% of the diameter. For this reason, the claim limitations are fully met in this regard.

With regard to claim 6 specifically, it is noted that the limitation of exposing the body to a laser is a method limitation. For this reason, it is not afforded much patentable weight in that it is product-by-process limitation; see MPEP 2113, which is incorporated herein by reference there. In particular, if the product is not considered to be identical, it is considered to be at least substantially identical to the extent that is it clearly obvious thereover.

With regard to claim 8, it is noted that collagen, one of the agents of carriers, is a polymer of amino acids as are all proteins. For this reason, the claim language is fully met. Furthermore, the delivery matrix of Brown can contain other polymers; see page 13, lines 3-14.

With regard to claim 11, the barrier as claimed is present by the top end of the groove, which converges into a slit. Therefore, the present claim is at least obvious in view of Brown et al, which clearly suggests it.

With regard to claim 22, Applicant is directed to see elements (114) of Figure 18.

With regard to claim 23, Burkoth fails to disclose the use of an adhesive with the filaments as claimed. However, since Burkoth discloses using other elements therewith (see page 13) and since the use of adhesive provides no stated advantage or unexpected/unobvious result, it is the Examiner's position that it would have been *prima*

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*fascia* obvious to use an adhesive with or on the drug depot of Burkoth in order to better secure it to the stent body. Alternatively, with regard to claim 23 specifically, it is noted that the limitation of adhesively bonding of the filament in the groove is a method limitation that does not necessarily require an adhesive; in other words, it only requires an adhesive functionality. For this reason, it is not afforded much patentable weight in that it is product-by-process limitation; see MPEP 2113, which is incorporated herein by reference there. In particular, if the product is not considered to be identical, it is considered to be at least substantially identical to the extent that it is clearly obvious thereover.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burkoth et al (WO 98/23228) and Kaplan as applied *supra* in further view of Fischell et al (US 5,722,984). Burkoth et al at least renders obvious the claim language as set forth above. Burkoth fails to teach the use of a radioactive isotope as claimed. Fischell et al, however, teaches that it was known to use radioactive isotopes in stent devices in order to reduce cell proliferation and restenosis; see especially the abstract. Hence, it is the Examiner's position that it would have been obvious to use a radioactive isotope along with or in place of the active agents of Burkoth et al in order to reduce cell proliferation and restenosis as taught by Fischell et al.

### ***Response to Arguments***

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

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**Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic  
Primary Examiner  
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